



DEPARTMENT OF HEALTH & HUMAN SERVICES

94898d  
Food and Drug Administration

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

June 15, 2004

Ref: 2004-DAL-WL-18

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

Mr. Patrick O'Ray, CEO & President  
Specialty Brands, Inc.  
P.O. Box 51467  
Ontario, CA 91761-1057

Dear Mr. O'Ray:

An inspection of your food manufacturing facility located at 601 E. 3<sup>rd</sup> Street, Lampasas, Texas, was conducted on February 26 and March 1, 2004 by Investigators from the Food and Drug Administration (FDA). The inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Section 589.2000 – Animal Proteins Prohibited in Ruminant Feed (21 CFR 589.2000). This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE).

Our inspection revealed that your firm sells its production stream waste for use as animal feed and that it contracted with [REDACTED] to dispose of this manufacturing process stream waste. [REDACTED] used this process stream waste as animal feed for ruminants.

At the close of the inspection, a list of inspectional observations (FDA 483) was issued to your firm and discussed with Mr. Anthony E. Rocz, Plant Manager. The following violation was observed during the inspection:

Products that contain protein derived from mammalian tissues and that are intended for use in animal feed must be labeled with the cautionary statement, "Do not feed to cattle or other ruminants," as required by 21 CFR 589.2000(d)(1). For example, your firm manufactures Mexican specialty food products such as tortillas, taquitos, and burritos that contain beef. The production process stream waste includes ground corn, product shells, and filling material, it is then placed in a transportable bin for disposal by feeding to livestock. This transportable waste bin did not bear the cautionary statement "Do Not Feed to Cattle or Other Ruminants."

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Specialty Brands, Inc.  
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Because your manufacturing stream waste did not bear this cautionary statement, these products are misbranded within the meaning of section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or injunction.

We are in receipt of a letter from Mr. Anthony E. Rocz, Plant Manager, dated March 2, 2004, in which he stated that your factory was under a contract with [REDACTED] to remove and dispose of the production stream waste generated at the factory since April 15, 2003. Our investigators conveyed to Specialty Brands, Inc., on February 24, 2004, that the disposal container was not properly labeled to indicate that the material is not to be fed to cattle or other ruminants in accordance with the BSE regulation. On February 26, 2004, our investigators returned to your plant and conveyed to Mr. Rocz that earlier that morning they observed cattle consuming the manufacturing stream waste supplied by your firm to [REDACTED]. The practice of supplying process stream waste to [REDACTED] was indefinitely suspended on February 26, 2004. At that time, an alternative waste removal service was obtained to dispose of the process stream waste in a sanitary landfill facility and each load would be logged, a manifest detailing the pounds of process waste disposed would be generated, and a certification of proper disposal is to be provided for the record. This alternative stream waste disposal process appears to be acceptable. Your letter also states that your corporate Food Safety and Quality Assurance department is in the process of drafting a corporate wide policy to ensure that all of your factories are in compliance with the BSE regulation.

It is necessary for you to take prompt action on this matter now. Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific actions you have taken to prevent the recurrence of the violations, and when those actions were taken or will be taken at your other corporate facilities having similar disposal plans. Your reply should be sent to Edwin Ramos, Compliance Officer, at the above stated address. If you have any questions concerning this letter, you may contact Mr. Ramos at 214-253-5218.

Sincerely,

  
Michael A. Chappell  
Dallas District Director

cc: Specialty Brands, Inc.  
Mr. Anthony E. Rocz, Plant Manager  
601 E Third Street  
Lampasas, TX 76550-2903